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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,667	08/18/2000	John S. Fox	65446-0053	6732

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EXAMINER

CHEU, CHANGHWA J

ART UNIT PAPER NUMBER

1641

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/641,667

**Applicant(s)**

FOX, JOHN S.

**Examiner**

Jacob Cheu

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2004.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-116 is/are pending in the application.  
4a) Of the above claim(s) 18-102 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-17 and 103-116 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.  
4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. 1/26/2004.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_.

Art Unit: 1641

### **DETAILED ACTION**

Applicant's amendment filed on 2/3/2004 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claim 117 is cancelled.
2. Claims 103-116 are added to the instant application.
3. Currently, claims 1-17 and 103-116 are under examination.
4. Affidavit filed on 11/24/2003 under Rule 1.131 has been received and entered into record.

### ***Claim Rejections - 35 USC § 112***

#### ***Enablement***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
2. Claims 1-17 and 103-116 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), enablement requires that the specification teach those skilled in the art to make and use the invention without undue experimentation. Factors to be considered in determining, whether a disclosure would require undue experimentation include 1) the nature of the invention, 2) the state of the prior art,

Art Unit: 1641

3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the quantity of experimentation necessary, 7) the relative skill of those in the art, and 8) the breadth of the claims.

The instant invention recites an assay to determine an analyte in a sample by use of magnetic characteristics in response to applied magnetic field force. Applicant recited four main characteristics, including (1) swing time; (2) hysteresis loop (a. saturation magnetization, b. remnant magnetization, c. coercive force); (3) spatial orientation and (4) magnitude. Applicant further claims that one or more of the above mentioned features could be used to determine the (1) presence, (2) location, (3) orientation and (4) quantity of the target-probe complex, and the target molecules. (See claim 1 and 116) In the specification, application also outlines a “*hypothetical* ferromagnetic material” in illustrating the magnetization response. (See page 15, line 15-20; Figure 2) Figure 3 depicts various behaviors of different magnetic materials in response to the magnetization. The examiner acknowledged that applicant first have the instant “conception” around 9/25/1997 (See affidavit, page 5, paragraph 28-30) Nevertheless, it appears that the current results, particularly from Figure 4-6, do not support the notion that the inventive concepts have been reduced to practice. Applicant indicates that Figure 4 illustrating a typical output of an embodiment of a magnetic detection for a ferrofluid-labeled DNA sample, and Figure 5-6, for quantitation of DNA and RNA, respectively. However, examiner notices that applicant used the term “RMU” (relative magnetic unit) in all these three results. It is not clear what defines the RMU, and how do those swing time, magnetization, hysteresis loop or magnitude reflect in the RMU? (See page 28, 22-24) Furthermore, it appears that all the data from Figure 4-6, merely represent *one* type of unspecified feature, assuming relating one of the four features recited in the claim. Then the next issue is whether the rest of the recited magnetic features would behave similarly as in Figure 4-6, and be reliable for detection on DNA or RNA. Additionally, applicant also recites that the claimed magnetic features could be used to detect the (1) presence, (2) location, (3) orientation and (4) quantity of the target-probe complex, and the target molecules. Figure 4-6, alone or in combination, may be reflecting the (1) presence and (4) quantity outcomes of the target molecules in response to the magnetic field. However, it is not clear about how one skilled in the art would use the instant invention to detect the target

Art Unit: 1641

molecules by use of the features of (3) orientation and (2) location in response to the magnetic field. The current data (Figure 4-6) do not sufficient support the notion that “orientation” or “location” can be used to detect the target molecule. The specification does not teach how to extrapolate data obtained from the instant experimentation, i.e. Figure 4-6, to the development of reliable model commensurate in scope with the claimed invention. In view of the aforementioned lack of predictability in the art, undue experimentation would be required to practice the claimed methods with a reasonable expectation of success, absent a specific and detailed description in the applicant’s specification of how to effectively practice the recited method and absent working examples.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-17 and 103-116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 15, “as well as” is vague and indefinite. Applicant needs to positively recite the step for the determining magnetic characteristics in the claim.

Claim 1, line 16, “identify some one or more’ is vague and indefinite. It is unclear what “some” applicant refers to.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1641

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 5, 8, 9, 16-17 and 112-116 are rejected under 35 U.S.C. 102(b) as being anticipated by Rohr, Thomas (US 5445970).

Rohr teaches an assay to determine the presence or amount of analyte in a test sample. Rohr teaches contacting the test sample with an immobilized probe (i.e. specific affinity to the analyte) with a magnetically-labeled reagent to form analyte-probe complex, and applying a magnetic field to measure the presence or amount of the analyte in the test in the sample in response to the magnetic force. (See claim 1-6; Figure 6-14; Table 2-3) The magnetic materials could be superparamagnetic particles, or inherently including materials having magnetic characteristics, such as paramagnetic or ferromagnetic. (See example 1) The magnetic particles are visually identifiable, i.e. neodymium-iron-boron. (See example 1)

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

Art Unit: 1641

3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 3, 4, 6, 7, 10-11, 12-14, 110-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rohr as unpatentable in view of Pirrung et al. (US 5143854)

Rohr's reference has been discussed but is silent in teaching disposed probes in an addressable array for analysis. Pirrung et al. teach a method of assaying multiple peptides binding to receptors by use of addressable array system, i.e. known locations, for convenience and economy. (See abstract, Figures 1-8; col. 1, line 16-18) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Rohr with the array system as taught by Pirrung et al. since it is well-known in the field for purposes mass detection of analytes in interest in a convenient and economical way.

Although, Rohr does not specifically teach using a plurality of magnetic fields having different directions, it is an inherent characteristic that such plurality of magnetic fields arrangement would be able to generate different directions of magnetic force.

6. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rohr in view of Moeremans et al. (EP 0165633).

Rohr reference has been discussed supra but they does not specifically teach contacting the target molecule or molecule complex with a non-magnetic colloid. Moeremans et al. teach contacting samples with colloid metal particles for better affinity and selectivity to the target molecules. (page 2, line 31-35; claim 2) The colloid metals include non-magnetic metals, such as platinum, gold, silver, and copper. Supra. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Rohr et al. with the non-magnetic colloid materials to a complex with the

Art Unit: 1641

target molecule as taught by Moeremans et al. for a better affinity and selectivity in detecting the target molecule in a sample.

***Response to Applicant's Argument***

7. The rejections of claims 1-17 as anticipated under 35 U.S.C. 102 (a) over Baselt et al. (US 5981297) and Shieh et al. (US 6057167) prior arts are withdrawn.

Applicant's affidavit has been considered and it shows that applicant conceptualized the magnetic-label probe in detecting target molecule around May, 1994. (See affidavit page 1, paragraph 2; Photocopy of lab note, page 10- 10/16/1995) Accordingly, applicant's affidavit antedated both Baselt and Shieh references under 35 U.S.C 102 (a).

The newly Rohr et al. reference in this Office Action has a publication date on August 29, 1995, which is more than one year earlier than the current filing date on August 18, 2000 (priority date, August 21, 1999) Therefore, the 102 (b) rejection is deemed proper and cannot be antedated by applicant's affidavit under Rule 1.131.

***Conclusion***

8. No claim is allowed.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37



Art Unit: 1641

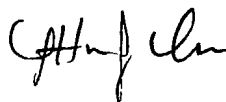
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

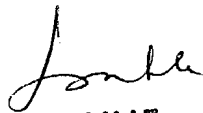
Jacob Cheu



Examiner

Art Unit 1641

March 17, 2004



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03/18/04